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PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

ALFRED S. LEWIN

LYNN C. SHAW

MARIA B. GRANT

Group Art Unit: 1632

Examiner: Unknown

Serial No.: 09/847,601

Atty. Dkt. No.: 4300.014100

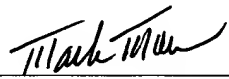
Filed: May 1, 2001

For: ADENO-ASSOCIATED VIRUS-
DELIVERED RIBOZYME
COMPOSITIONS AND METHODS FOR
THE TREATMENT OF RETINAL
DISEASES

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING 37 C.F.R. § 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:	
September 12, 2001 Date	 Signature

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Assistant Commissioner is hereby authorized to deduct said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/4300.014100.

This application is a continuation-in-part application of Serial No. 09/063,667, filed April 21, 1998 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/063,667.

Applicants respectfully request that the listed documents be made of record in the present case.

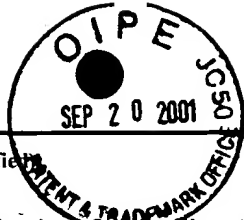
Respectfully submitted,

Date: September 12, 2001



Mark D. Moore, Ph.D.
Reg. No. 42,903
WILLIAMS, MORGAN & AMERSON
7676 Hillmont, Suite 250
Houston, Texas 77040
(713) 934-4084
(713) 934-7011 (via facsimile)

AGENT FOR APPLICANTS



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

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(Use several sheets if necessary)

Atty. Docket No.
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Alfred S. Lewin, Lynn C. Shaw and Maria B. GrantFiling Date:
May 1, 2001Group:
1632U.S. Patent Documents
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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,987,071	01/22/91	Cech <i>et al.</i>			
	A2	5,037,746	08/06/91	Cech <i>et al.</i>			
	A3	5,093,246	03/03/92	Cech <i>et al.</i>			
	A4	5,116,742	05/26/92	Cech <i>et al.</i>			
	A5	5,498,539	03/12/96	Harrison <i>et al.</i>			
	A6	5,639,655	06/17/97	Thompson <i>et al.</i>			
	A7	5,646,020	07/08/97	Swiggen <i>et al.</i>			
	A8	5,646,031	07/08/97	DeYoung <i>et al.</i>			

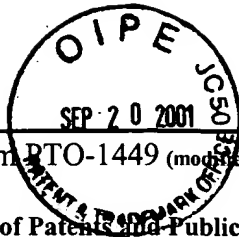
Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 95/04142	02/09/95	PCT			
	B2	WO 97/11169	03/27/97	PCT			
	B3	WO 97/32024	09/04/97	PCT			
	B4	WO 98/48009	10/29/98	PCT			
	B5	WO 98/48027	10/29/98	PCT			

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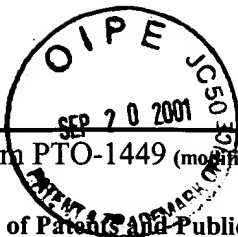
Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Alfione <i>et al.</i> , "In vivo model of adeno-associated virus vector persistence and rescue," <i>Journal of Virology</i> , 70:3235-3241, 1996.
	C2	Altschuler <i>et al.</i> , "A method for generating transcripts defined with 5' and 3' termini by autolytic processing," <i>Gene</i> , 122:85-90, 1992.
	C3	Al-Ubaidi <i>et al.</i> , "Photoreceptor degeneration induced by the expression of simian virus 40 large tumor antigen in the retina of transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> , 89:1194-1198, 1992.
	C4	Cech, "Self-splicing of Group I introns," <i>Annu. Rev. Biochem.</i> , 59:543-568, 1990.
	C5	Chakravathy <i>et al.</i> , "Nitric oxide synthase activity and expression in retinal capillary endothelial cells and pericytes," <i>Curr. Eye Res.</i> , 14(4):285-294, 1995.
	C6	Chen <i>et al.</i> , "The human blue opsin promoter directs transgene expression in short-wave cones and bipolar cells in the mouse retina," <i>Proc. Natl. Acad. Sci. USA</i> , 91(7):2611-2615, 1994.
	C7	Chiu <i>et al.</i> , "A sequence upstream of the mouse blue visual pigment gene directs blue cone-specific transgene expression in mouse retinas," <i>Visual Neuroscience</i> , 11(4):773-780, 1994.
	C8	Cipolla, Porter and Osol, "High glucose concentrations dilate cerebral arteries and diminish myogenic tone through an endothelial mechanism," <i>Stroke</i> , 28(2):405-411, 1997.
	C9	Cosentino <i>et al.</i> , "High glucose increases nitric oxide synthase expression and superoxide anion generation in human aortic endothelial cells," <i>Circulation</i> , 96(1):25-28, 1997.
	C10	Crystal, "Transfer of genes to humans: early lessons and obstacles to success," <i>Science</i> , 270:404-410, 1995.
	C11	Daiger, Sullivan and Rodriguez, "Correlation of phenotype with genotype in inherited retinal degeneration," <i>Behavioral and Brain Sciences</i> , 18:452-467, 1995.
	C12	DesJardin and Hauswirth, "Developmentally important DNA elements within the bovine opsin upstream region," <i>Investigative Ophthalmology & Visual Science</i> , 37(1):154-165, 1996.
	C13	Drenser <i>et al.</i> , "Ribozyme mediated degradation of the P23H and S334Ter mutant mRNAs associated with ADRP," <i>Investigative Ophthalmology & Visual Science</i> , 38(4):S441, Abstract 2085, 1997 (Annual Mtg. Of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA, May 11-16, 1997).

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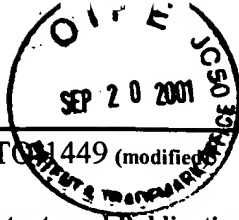
Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C14	Drenser <i>et al.</i> , "Ribozyme mediated destruction of an messenger-RNA causing retinitis pigmentosa," <i>Investigative Ophthalmology & Visual Science</i> , 37(3):S10, Abstract 42, 1996.
	C15	Drenser <i>et al.</i> , "Ribozyme-targeted destruction of RNA associated with autosomal-dominant retinitis pigmentosa," <i>Investigative Ophthalmology & Visual Science</i> , 39(5):681-689, 1998.
	C16	Flannery <i>et al.</i> , "Efficient photoreceptor-targeted gene expression <i>in vivo</i> by recombinant adeno-associated virus," <i>Proc. Natl. Acad. Sci. USA</i> , 94(13):6916-6921, 1997.
	C17	Flotte <i>et al.</i> , "Stable <i>in vivo</i> expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Proc. Natl. Acad. Sci. USA</i> , 90(22):10613-10617, 1993.
	C18	Gade <i>et al.</i> , "Nitric oxide mediates hyperglycemia-induced defective migration in cultured endothelial cells," <i>Journal of Vascular Surgery</i> , 26(2):319-326, 1997.
	C19	Goldstein, Ostwal and Roth, "Nitric oxide: a review of its role in retinal function and disease," <i>Vision Res.</i> , 36(18):2979-2994, 1996.
	C20	Hangai <i>et al.</i> , "Inducible nitric oxide synthase in retinal ischemia-reperfusion injury," <i>Exp. Eye Res.</i> , 63(5):501-509, 1996.
	C21	Hauswirth <i>et al.</i> , "Adeno-associated virus delivery of an opsin promoter driven reporter gene to the mouse and rabbit retina," <i>Gene Therapy</i> , 2(Supp. 1):S2, Abstract 6, 1995.
	C22	International Search Report dated February 1, 1999 (PCT/US98/07968) (4300.011510).
	C23	International Search Report dated February 16, 1999 (PCT/US98/08003) (4300.011410).
	C24	Kaplitt <i>et al.</i> , "Long-term gene expression and phenotypic correction using adeno-associated virus vectors in the mammalian brain," <i>Nature Genetics</i> , 8:148-154, 1994.
	C25	Kessler <i>et al.</i> , "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein," <i>Proc. Natl. Acad. Sci. USA</i> , 93:14082-14087, 1996.
	C26	Kido <i>et al.</i> , "Use of a retroviral vector with an internal opsin promoter to direct gene expression to retinal photoreceptor cells," <i>Current Eye Research</i> , 15:833-844, 1996.
	C27	Koizumi, Kiroyuki and Eiko, "Ribozymes designed to inhibit transformation of NIH3T3 cells by the activated c-Ha-ras gene," <i>Gene</i> , 117:179-184, 1992.

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C28	Komatsu <i>et al.</i> , "A new type of hairpin ribozyme consisting of three domains," <i>Biochemistry</i> , 36(32):9935-9940, 1997.
	C29	Lem <i>et al.</i> , "Tissue-specific and developmental regulation of rod opsin chimeric genes in transgenic mice," <i>Neuron</i> , 6:201-210, 1991.
	C30	Lewin <i>et al.</i> , "Ribozyme rescue of photoreceptor cells in a transgenic rat model of autosomal dominant retinitis pigmentosa," <i>Nature Medicine</i> , 4(8):967-971, 1998.
	C31	Li <i>et al.</i> , "Cone-specific gene transfer and expression using human red/green opsin promoter in a recombinant AAV," <i>IOVS</i> , 39(4):S721, 3311-B137, 1998.
	C32	Little and Lee, "Generation of a mammalian cell line deficient in glucose-regulated protein stress induction through targeted ribozyme driven by a stress-inducible promoter," <i>The Journal of Biological Chemistry</i> , 270(16):9526-9534, 1995.
	C33	Millington-Ward <i>et al.</i> , "Strategems <i>in vivo</i> for gene therapies directed to dominant mutations," <i>Human Molecular Genetics</i> , 6(9):1415-1426, 1997.
	C34	Ojwang <i>et al.</i> , "Inhibition of human immunodeficiency virus type 1 expression by a hairpin ribozyme," <i>Proc. Natl. Acad. Sci. USA</i> , 89:10802-10806, 1992.
	C35	Ostwald <i>et al.</i> , "Effect of nitric oxide synthase inhibition on blood flow after retinal ischemia in cats," <i>Investigative Ophthalmology & Visual Science</i> , 36(12):2396-2403, 1995.
	C36	Raymond <i>et al.</i> , "Expression of rod and cone visual pigments in goldfish and zebrafish: a rhodopsin-like gene is expressed in cones," <i>Neuron</i> , 10:1161-1174, 1993.
	C37	Ross <i>et al.</i> , "Gene therapy in the United States: A five year status report," <i>Human Gene Therapy</i> , 7:1781-1790, 1996.
	C38	Sharma <i>et al.</i> , "Enhance expression of inducible nitric oxide synthase in murine macrophages and glomerular mesangial cells by elevated glucose levels: Possible mediation <i>via</i> protein kinase C ⁺ ," <i>Biochem. Biophys. Res. Comm.</i> , 207(1):80-88, 1995.
	C39	Steinberg <i>et al.</i> , "Transgenic rat models of inherited retinal degeneration caused by mutant opsin genes," <i>Inv. Ophth. Vis. Sci.</i> , 37:S698, Abstract, 1996.
	C40	Timmers, Newton and Hauswirth, "Synthesis and stability of retinal photoreceptor mRNAs are coordinately regulated during bovine fetal development," <i>Exp. Eye Res.</i> , 56:257-265, 1993.

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Other Art

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C41	van Ginkel and Hauswirth, "Parallel regulation of fetal gene expression in different photoreceptor cell types," <i>The Journal of Biological Chemistry</i> , 269(7):4986-4992, 1994.
	C42	Verma and Somia, "Gene therapy – promises, problems and prospects," <i>Nature</i> , 389:239-242, 1997.
	C43	von Weizsäcker, Blum and Wands, "Cleavage of hepatitis B virus RNA by three ribozymes transcribed from a single DNA template," <i>Biochemical and Biophysical Research Communications</i> , 189(2):743-748, 1992.
	C44	Xiao <i>et al.</i> , "Efficient long-term gene transfer into muscle tissue of immunocompetent mice by adeno-associated virus vector," <i>Journal of Virology</i> , 70(11):8098-8108, 1996.
	C45	Xing and Whitton, "An anti-lymphocytic choriomeningitis virus ribozyme expressed in tissue culture cells diminishes viral RNA levels and leads to a reduction in infectious viral yield," <i>Journal of Virology</i> , 67(4): 1840-1847, 1993.
	C46	Yu <i>et al.</i> , "A hairpin ribozyme inhibits expression of diverse strains of human immunodeficiency virus type 1," <i>Proc. Natl. Acad. Sci. USA</i> , 90:6340-6344, 1993.
	C47	Yu <i>et al.</i> , "In vitro and in vivo characterization of a second functional hairpin ribozyme against HIV-1," <i>Virology</i> , 206(1):381-386, 1995.
	C48	Yung, "Molecular modulation of vascular endothelial growth factor (VEGF) expression in glioma cells by ribozymes," <i>Neurology</i> , 48(3 Suppl. 2):A22, Abstract VI3.001, 1997.
	C49	Zolotukhin <i>et al.</i> , "A humanized green fluorescent protein cDNA adapted for high-level expression in mammalian cells," <i>Journal of Virology</i> , 70(7):4646-4654, 1996.
	C50	Co-pending U.S. Patent Application Serial No. 09/063,792, filed April 21, 1998 (4300.011400).
	C51	Report and recommendations of the panel to assess the NIH investment in research on gene therapy, Orkin and Motulsky, co-chairs, National Institutes of Health, December 1995.
	C52	Crooke, S.T., "Vitravene – Another piece in the mosaic," <i>Antisense and Nucleic Acid Devel.</i> , 8:vii-viii, 1998.
	C53	Gewirtz <i>et al.</i> , "Facilitating oligonucleotide delivery: Helping antisense deliver on its promise," <i>Proc. Natl. Acad. Sci. USA</i> , 93:3161-63, April 1996.

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	C54	Lyngstadaas <i>et al.</i> , "A synthetic, chemically modified ribozyme eliminates amelogenin, the major translation product in developing mouse enamel <i>in vivo</i> ," <i>EMBO J.</i> , 14:5224-29, 1995
	C55	Stein, "Keeping the biotechnology of antisense in context," <i>Nat. Biotechnol.</i> , 17:209, March 1999
	C56	Stull <i>et al.</i> , "Antigene, ribozyme and aptamer nucleic acid drugs: Progress and prospects," <i>Pharm. Res.</i> , 12:465-83, April 1995
	C57	Christoffersen <i>et al.</i> , "Ribozymes as human therapeutic agents," <i>J. Med. Chem.</i> , 38:2023-37, June 1995
	C58	LaVail <i>et al.</i> , "Ribozyme rescue of photoreceptor cells in P23H transgenic rats: Long-term survival and late-stage therapy," prepublished online as <i>Proc. Natl. Acad. Sci. USA Early Edition</i> , 10.1073/pnas210319397, September 26, 2000

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